REMARKS / ARGUMENTS

Claims 7 and 9 have been amended.

Claims 1 – 15 remain pending in the application.

The Examiner's rejection of claims 1-15 under 35 USC (a) over Kobozev in view of Eini is not understood. In particular, in the International Preliminary Examination Report of the corresponding PCT application (PCT/US02/34245), which contains the same independent claims as in the instant application, the Examiner stated that "the prior art does not teach or fairly suggest a two-unit system and method for at least one of transducing vaginal conditions, affecting vaginal or body conditions, and stimulating perineal musculature and nerves where the system includes a combination probe, transceiver and power source forming a first single unit and combination controller and transceiver forming a second single unit, where the combination probe, transceiver and power source includes means for at least one of sensing vaginal conditions, delivering signals or medication, and stimulating musculature or nerves, and where a wireless signal feedback loop is provided between the two units".

Applicants' independent claims, which define a two-unit system, require:

a) a single, separate unit in the form of a portable non-implanted, intravaginally containable combination probe, transceiver and power source (21,34), which unit is provided with 2-way wireless communication means (36),

b) a single, separate unit in the form of a combination controller and transceiver 22 that is provided with wireless means (36'), and

c) wherein a wireless signal feedback loop is provided between the controller 22 and the probe 21.

In other words, the system of the present application requires two separate units, namely a separate combination probe, transceiver and power source 21, 34, and a separate combination controller and transceiver 22, with a wireless signal feedback loop being provided between them.

The electrical gastro-intestinal tract (GIT) stimulator of Kobozev makes broad mention only, without any support or substantiation, of possible vaginal use. However, applicants respectfully submit that in fact Kobozev could not be suitable for vaginal use, as will be discussed in detail subsequently.

Kobozev is clearly directed and claimed as a gastro-intestinal tract stimulator. However, applicants respectfully submit that it is not physically possible to access the gastro-intestinal tract through the vagina; nor is it possible to access the vagina through the gastro-intestinal tract. Therefore, applicants furthermore submit that any statement in Kobozev that a GIT stimulator can be used in the vagina are not founded and that one of ordinary skill in the art would ignore such statements. This will be further addressed below.

As further background for an understanding of the differences between the GIT stimulator of Kobozev and the system of the present application, it should be noted that the Kobozev device applies electrical stimulation to the involuntary organs of the gastro-intestinal tract, whereas the device of the present application applies electrical stimulation to the voluntary pelvic floor muscles of the vagina rather than to the voluntary vaginal organs. One must also keep in mind that the organs of the gastro-intestinal tract share a common purpose, namely to digest food and liquid and dispel the waste matter as an involuntary motor evacuative function. In contrast, the URO genital organs of the vaginal region do not share a common function; they are voluntary, and

highly sensitive to stimulation.

Kobozev, in column 2, lines 14-22, expresses concern about patients health and safety with regard to the side-effects and contra-indication when he points out differences between his GIT electrical stimulator and the stimulator described in RU No. 936931. In view of the fact that Kobozev recognizes that there are safety concerns associated with the application of electrical stimulus to involuntary organs, the same critical health and safety concerns about side-effects and contra-indications would preclude use of the Kobozev device on the vaginal organs. Therefore, it is again respectfully submitted that one of ordinary skill in the art would not even consider Kobozev for vaginal use. As further evidence of the unsuitability of the Kobozev device for vaginal use, applicants respectfully address the Examiner's attention to, for example, column 2, lines 17-20, column 6, lines 48-50, and column 9, line 19, where Kobozev makes it abundantly clear that pain and musculature convulsion can and do occur when a GIT electrical stimulator passes through some sections of the GIT. Not only would pain alone make the Kobozev device unsuitable for vaginal use, but in addition the uro-genital organs of the vaginal region are not only highly sensitive to stimulation, they are prone to involuntary contractions and spasms that cause multiple symptoms of urinary urgency, commonly called overactive bladder (OAB) and/or urinary stress incontinence (USI).

In the beginning of Item 7. of page 3 of the Office Action, the Examiner states that "Kobozev teaches a mucous membrane stimulator for transducing and affecting mucous membrane conditions within the vagina". However, applicants respectfully disagree with this statement. In particular, Kobozev's only reference to the use of electrical stimulation of mucous membranes is in the introductory portion in column 1,

under the heading "AREA OF ENGINEERING", where he states that his invention relates to medical technology and can be used for electrical stimulation of GIT organs and mucous membranes in abdominal surgery and for treatment of therapeutic type diseases. Thus, Kobozev explicitly limits his teaching about the use of GIT stimulation of mucous membranes to abdominal surgery.

As indicated above, in this same AREA OF ENGINEERING section of Kobozev, he teaches that his electrical stimulation device is for organs of the gastro-intestinal tract and for treatment of therapeutic type diseases. Kobozev elaborates on therapeutic type diseases in the INDUSTRIAL APPLICABILITY section of his patent in column 9, lines 17-49, with lines 40-49 again specifically limiting the treatment to therapeutic type diseases with GIT electrical stimulators to only those diseases of the gastro-intestinal tract. Thus, it is again respectfully submitted that Kobozev provides no teaching or suggestion of "a mucous membrane stimulator for transducing and affecting mucous membrane conditions within the vagina", as stated by the Examiner. Applicants would again like to point out that all of the emphasis and all of the support in Kobozev, including in particular the claims, is clearly directed to an electrical gastro-intestinal stimulator which, in order to function, must move through the GIT, autonomously. For example, the Examiner's attention is directed to column 3, lines 60-67, in the last full paragraph of the SUMMARY OF THE INVENTION, where he states that the main positive effect of GIT stimulators is their ability to restore motor-evacuative function of the GIT. Kobozev then goes on to state that his electrical GIT stimulator, "in contrast to what is known, is capable not only to move autonomously through the gastro-intestinal tract, but also to selectively influence GIT sites by intermittently applying electrical pulses to the sites, consecutively restoring functions of organs along the whole length of

the GIT". In this regard, it is critical to understand that the digestive function of the gastro-intestinal tract, and the motor-evacuation function of GIT organs are involuntary. Although one is able to start swallowing by choice, once the swallow begins it becomes involuntary. The digestive system is a series of hollow organs joined in a long twisting tube from the mouth to the anus. Inside this tube is a lining called mucosa or mucous membrane. The motor-evacuative function of the GIT is to move food and liquids down the gastro-intestinal tract, which averages 24 to 26 feet from the esophagus to the anus. The involuntary physiological activity of the GIT organs causes involuntary organ motion which is called peristalsis which looks like an ocean wave moving through the GIT tract.

In column 5, lines 48-67, and column 6, lines 1-14, Kobozev describes both the physiology and how his GIT stimulator operates. Essentially, the GIT electrical stimulator of Kobozev is designed to move down the gastro-intestinal tract in order to sense involuntary peristaltic wave action, or the lack of involuntary peristaltic wave movement. If no movement, or low movement, of peristaltic waves is sensed, this input is sent to the control unit 18. The control unit makes certain statistical comparisons in order to autonomously turn-on the electrical stimulator to apply an electrical stimulus to the GIT organs in order to restore motor-evacuative functions. Once sufficiently high motor-evacuative function is restored, the GIT stimulator is autonomously turned off and continues moving down the GIT tract until it again senses no or low peristaltic wave action, which then again triggers the control unit to turn-on and electrically stimulate the corresponding organ. It should be noted that if the GIT electrical stimulator of Kobozev were to be used autonomously to electrically stimulate the voluntary female organs, a woman would be in a constant state of pain, urination and stimulation, thus again

pointing out the non-suitability of the Kobozev stimulator for vaginal use.

In column 2, lines 17-22 and line 62, column 6, lines 48 and 49, and column 9, lines 17-22, Kobozev compares the differences about the side-effects, the safety and the efficacy when using different electrical GIT stimulators. For example, in the first sentence under the heading INDUSTRIAL APPLICABILITY in column 9, Kobozev states that the offered electrical GIT stimulator 10, in comparison with uncontrollable GIT stimulators reduces or eliminates side-effects, such as pain and muscle convulsions, "caused by the passage of the electrical stimulator 10 through certain GIT sections" (emphasis added). Thus, when considering side-effects, safety and efficacy between a GIT electrical stimulator and a pelvic floor electrical stimulator, the anatomy and physiology must be a concern. The levator ani, commonly called the pelvic floor muscles, and the vaginal organs and tissues are voluntary. In addition, the vaginal organs, tissue and vaginal orifice are especially sensitive to manual or electrical stimulation. The pelvic floor muscles are less than one foot in length and their function is to provide stationary support to hold the bladder, uterus and rectal organs in place. Electrical stimulation is applied to pelvic floor muscles for only short periods of time, for example approximately 15 minutes per session. If electrical stimulation is applied to the sensitive and voluntary female organs, one can expect an adverse or injurious effect. When pelvic floor muscles weaken, the bladder, the uterus and the rectum can slip from their moorings. They are pulled down by gravity and get squeezed into the lower regions of the pelvis. If the pelvic floor muscles are damaged, the bladder and rectum can bulge into the vagina and the uterus can slip into the vaginal canal; this is called vaginal or rectal prolapse. A simple "preventative" program, including pelvic floor muscle exercise, may be all that is needed to stem the decline of the pelvic floor

muscles.

The use of an autonomous and downwardly mobile GIT electrical stimulation device to electrically stimulate vaginal organs, rather than stimulating the voluntary pelvic floor muscles, would likely result in damage to the very delicate female organs, the very sensitive vaginal tissue, and to the supporting pelvic floor voluntary muscles. For example, as indicated previously the voluntary pelvic floor muscles anchor the organs of the bladder, uterus and rectum in place. These are not involuntary organs and they certainly do not produce peristaltic waves. The autonomous GIT electrical stimulator of Kobozev must and is designed to move downwardly, and is configured with sensors to sense organ wave action; if no wave action is sensed, then the device is designed to autonomously turn-on an electrical stimulus to restore involuntary organ function. Absent such an organ's wave action, the device would autonomously continue to apply the electrical stimulus. Therefore, applying the same requisite downward movement toward the very sensitive tissue of the vaginal orifice, the electrical stimulus could easily result in a burn or a painful shock. Due to the fundamental anatomical and physiological differences between the involuntary nature of the organs of the gastro-intestinal tract, and the voluntary nature of the vaginal muscles and organs, it is again respectfully submitted that one of ordinary skill in the art would not look to a GIT stimulator when designing a system for vaginal use.

The Examiner has made further statements concerning Kobozev that applicants would like to traverse. For example, in Item 7. the Examiner indicates that the stimulator of Kobozev is provided with "a transceiver formed by control unit 18, transmitter 14 and receiver 22'. However, applicants respectfully submit that there is not teaching or suggestion in Kobozev, either in the drawings or in the specification, that

his control unit 18, transmitter 14 and receiver 22 are a transceiver. In particular, a transceiver is bi-directional so that it can simultaneously transmit and receive a signal. However, Kobozev clearly indicates that the transmitter 14 and receiver 22 of his stimulator are two separate and distinct components, rather than being bi-directional or two-way. In fact, Kobozev goes into great detail as to the inputs and outputs going from the receiver to the control unit to the transmitter, or from the control unit to the transmitter, etc. In Fig. 2, Kobozev specifically identifies 18 as the control unit but he merely identifies 14 as a transmitter, and 22 as a receiver. The Examiner's attention is also directed to claims 1-4, 6-11, 14-16, 18 and 19, where Kobozev specifically identifies these separate components as "control unit", "receiver", "receiver device", "device for receiving signals", "transmitter", "transmitter device", "transmitter device for sending signals", and "device for transmitting signals". It is respectfully submitted that the disclosure of Kobozev provides no teaching or suggestion that these components form a transceiver that can act simultaneously as both a transmitter and a receiver, as required by applicants claims.

At the top of page 4 of the Office Action, the Examiner also states that "the transceiver is provided with two-way wireless communication means for transmitting information that is transduced to an external unit and for receiving control and programming signals from an external unit". However, applicants respectfully submit that Kobozev provides no teaching or suggestion regarding "two-way wireless" communication. For example, in column 7, lines 62-64, and column 9, lines 37-40, Kobozev teaches that the transmitter 14 has the capability to output a signal to an external receiver (not shown) for medical supervision and diagnostics. Furthermore, in column 2, lines 53, 54 and 63-67, column 3, lines 33 and 34, and column 6, line 67, to

column 7, line 1, Kobozev specifies that the receiver 22 receives a signal from an external unit and not from the transmitter 14. With regard to the Examiner statement that the purported transceivers two-way wireless communication capability to send and receive signals from an external source, it is furthermore submitted that there is no disclosure in Kobozev to this effect, nor to any simultaneous two-way transmission of signals to, from or with an external unit. Rather, in Fig. 2 Kobozev teaches and illustrates that the control unit 18 and internal receiver 22 send input signals to the internal transmitter 14. No output signals of the internal transmitter 14 are illustrated in Fig. 2. In fact, as discussed above with regard to the transceiver, Kobozev teaches that the output signals of the internal transmitter 14 that are sent to an external unit are specifically for monitoring and for medical supervision. Kobozev in no way teaches or suggests that his internal transmitter 14 has a bi-directional or two-way capability to simultaneously transmit and receive a signal. In contrast, in column 2, lines 53 and 54, column 3, lines 32 and 33, and column 6, line 67 to line 1 of column 7, Kobozev teaches that a signal sent from an external unit is received by the internal receiver 22. This is a simplex or one-way directional receipt of a signal from an external unit. In addition, in column 8, lines 43-46, Kobozev teaches that a signal from an external transmitter is sent to the receiver 22 to switch-on or switch-off the electrical stimulator. Again, this is a one-way directional receipt of an external signal. Kobozev in no way teaches or suggests that the internal receiver 22 has a simultaneous bi-directional or two-way capability to simultaneously send and receive a signal with an external unit. It is respectfully submitted that combining two one-way devices does not form a transceiver even if the devices transmit and receive signals through a common connection such as a control unit. One is still left with one-way out and one-way in.

Such one-way out and one-way in signal transmission is comparable to a garage door opener, a walkie-talkie, or a CB radio; this is not interactive for two-way communication.

Near the top of page 4 of the Office Action the Examiner has also stated that "a wireless signal feedback loop is provided between the external units and the probe which may be an interactive or closed signal feedback wireless loop". Applicants respectfully submit that the method through which this interactivity and feedback between transmitter 14 and the external unit (not shown) is effected is significantly different from that which is claimed by the applicants. Specifically Kobozev's feedback loop is implemented using simplex, or one-way ?out and one-way in signal transmission devices. The applicants on the other hand use a duplex system that ensures simultaneous transmission of data between the two ports of the transceiver, which results in a feedback loop that is instantly much more efficient. Although Kobozev does specifically differentiate between sending and receiving external signals, he makes no claim that these are interactive or a duplex feedback loop, because in order to be interactive or a duplex signal feedback loop, a bi-directional or two-way capability to simultaneously send and receive a signal would be required. In column 4, lines 47-67, in column 5, lines 1-47, where the electrical circuitry of Figs. 2 to 5 of the GIT electrical stimulator are explained, Kobozev provides no teaching or suggestion that could lead to a conclusion that a wireless duplex signal feedback loop is provided between the external units and the probe that may be interactive or a duplex simultaneous signal feedback loop. Rather, as explained above, the receiver 22 and transmitter 14 have an external communications capability similar to that of a garage door opener, a walkie-talkie, or CB radio. However, this one-way back and forth signaling to or with an external source is not a two-way wireless signal feedback loop, which requires

simultaneous bi-directional signal transmission and reception.

As further evidence that the Kobozev stimulator cannot be considered for true vaginal use, Applicants would like to point out that as stated in the DETAILED DESCRIPTION OF EMBODIMENTS the Kobozev stimulator 10 is "configured to be administered orally to a patient", or to be introduced rectally; in neither case could the Kobozev GIT stimulator reach the vagina. This is completely understandable since the Kobozev stimulator is limited for use in, and movement through, the gastro-intestinal tract.

Applicants would also like to point out that the Kobozev device was developed over a decade later than the earlier Hochman, which is discussed in the introductory portion of the specification of the instant application. Although the Hochman disclosure had been available to Kobozev for quite a while, he made no use thereof since his electrical GIT stimulator was really not intended nor suitable for vaginal use as discussed above.

For the sake of completeness, applicants would like to point out that the intravaginal device of Eini must be "biased against a wall of the intravaginal cavity". This manner of operation is in distinct contrast to the moving stimulator of Kobozev. Kobozev requires, for example, that its GIT stimulator move autonomously through the gastro-intestinal tract, that peristaltic waves move the electrical stimulator 10 of Kobozev, and that the Kobozev electrical GIT stimulator reduces side-effects caused by the passage of the stimulator 10 through certain GIT sections. Thus, the principle of operation of the Kobozev stimulator is in distinct contrast not only to the Eini device but also to the system of the present application; in particular, an intravaginally containable probe must inherently sit in place while it operates, as evidenced by the requirement of

Eini that its device be biased against a wall of the intravaginal cavity. It is therefore respectfully submitted that pursuant to the last paragraph of MPEP section 2143.01 "the teachings of the references are not sufficient to render the claims prima facie obvious", since the proposed modification (using the teachings of the instant application) or combination of the prior art would change the principle of operation of the prior art invention being modified, mainly the requirement of Kobozev to be a moving stimulator.

In addition, in view of the foregoing discussion, applicants again respectfully submit that one of ordinary skill in the art would not look to the Kobozev GIT stimulator for any enlightenment with regard to an intravaginally containable system. Applicants' conclusion is supported by the attached declaration.

Although applicants respectfully submit that in view of the foregoing discussion the claims of the instant application should now be allowable, should the Examiner have any further concerns, other than of a formal nature, applicants respectfully request a personal interview with him in order to discuss the merits of the application.

Respectfully Submitted,

Robert W. Becker, Reg. No. 26,255
for applicants

ROBERT W. BECKER & ASSOCIATES
707 Highway 66 East, Suite B
Tijeras, NM 87059

Telephone: (505) 286-3511
Facsimile: (505) 286-3524

RWB:rc